Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1053408	**(X3) Date Survey Completed** 05/07/2024
Name of Provider or Supplier Rodgers Dermatology	**Street Address, City, State** 3880 Parkwood Blvd,Suite 102, Frisco, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicaid & Medicare Services) 116 form, laboratory proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (MOHS) slide interpretations at least twice annually for two of two testing events in 2022. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (MOHS) procedures. 2. Review of the laboratory's "Peer Review Schedule" revealed: "Peer review cases are to be sent Bi-Annually." Further review of the laboratory's proficiency testing records revealed twice annual accuracy assessment was NOT performed in 2022. The laboratory was asked to provide documentation for the semi-annual accuracy assessment events for 2022 and none were provided. The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations in 2022. 3. During an interview on 05/07/2024 at 10:35 am, the Histotechnicians after a review of the records confirmed the laboratory failed to perform semi-annual accuracy assessments 2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instruction manual, laboratory records, and confirmed in staff interview, the laboratory failed to monitor humidity requirements for the microscope, located in the laboratory director's office for seven of seven months in 2022, twelve of twelve months in 2023 and five of five months in 2024. Findings included: 1. During a tour of the laboratory director's office on 05/7 /2024 at 11:12 am, the surveyor observed the Olympus CX31 Biological Microscope (Serial #8G11261) on top of a cabinet. The microscope was used to perform slide reviews for histopathology diagnostic testing. 2. Review of Olympus CX31 Biological Microscope instruction manual page 20 revealed: "6 SPECIFICATIONS ... 9. Operating Environment ... Maximum relative humidity: 80% for temperatures up to 31C (88F)" 3. Review of the laboratory records for 2022, 2023 and 2024 revealed no documentation of humidity monitoring for the Olympus CX31 Biological Microscope. The laboratory was asked to provide documentation, and none was provided. 4. During an interview on 05/07/2024 at 11:25 am, the Histotechnicians were asked if humidity was monitored and documented, and they stated "No". This confirmed the above findings. Word Key: C - Celsius F- Fahrenheit
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instruction manual, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for ensuring 1 of 1 microscope was covered with a dust cover when not in use. Findings included: 1. During a tour of the laboratory director's office on 05/7 /2024 at 11:12 am, the surveyor observed the Olympus CX31 Biological Microscope (Serial #8G11261) on top of a cabinet uncovered. The microscope was not in use the day of inspection. 2. Review of Olympus CX31 Biological Microscope instruction manual revealed: "2 Maintenance and Storage ... 4. When not using the microscope, ensure that the frame is cooled down and store it in a locker or cover it with a dust cover." 3. During an interview on 05/07/2024 at 11:25 am, the Histotechnicians confirmed the laboratory failed to follow manufacturer's instructions for ensuring the microscope was covered with a dust cover when not in use.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, potassium hydroxide (KOH) patient logs, patient medical records, and in interview with staff, the laboratory failed to ensure two of seven patients KOH results were transcribed accurately to the final test report (random review 04/2024-05/2024). Findings included: 1. Review of the laboratory's policy "KOH Prep" stated: "KOH tests will be documented in the patient's chart as well as a running log, kept in the nurse's station." 2. A random review of "KOH Patient Log" from 04/2024 through 05/2024 revealed the following patient KOH results documented: Patient #1 Date: 05/01/2024; Patient Name: [XX]; Description of Findings: Tinea Versicolor POS Patient #2 Date: 05/06/2024; Patient Name: [XX]; Description of Findings: Positive The laboratory's practice was documenting the patient's result in the log and then transcribing it manually or by dictation in the patient's chart ("Visit Note"). The laboratory was asked to provide the above-mentioned patients charts to review the KOH results for those dates. The charts were provided, and KOH results were transcribed in the patients charts as follows: Patient #1: MRN (medical record number): MM0000020685; Visit Note date: 05/01/2024 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the truck. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: clustered spores and short wide hyphae." Patient #2: MRN: MM0000017602; Visit Note date: 05/06/2024 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the right lateral abdomen. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: clustered spores and short wide hyphae." The final report test results did not reflect results in the patient log. The laboratory failed to ensure test results were transcribed accurately when entered into the patient chart. 3. During an interview on 05/07/2024 at 10:11 am, the Histotechnician after a review of records confirmed the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of CMS 209 form, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for three of four testing persons (TP-2, TP-3, TP-4) who perform moderate complexity testing. Findings included: 1. Review of CMS 209 form listed TP-2, TP-3, and TP-4 as testing personnel who perform moderate complexity testing. 2. Review of the personnel records for TP-2, TP-3, and TP-4 revealed there were NO delegation of duties for testing persons engaged in moderate complexity testing by the laboratory director. The laboratory director failed to specify in writing the responsibilities for TP-2, TP-3, and TP-4 who performed moderate complexity testing. 3. During an interview on 05 /07/2024 at 9:58 am, the Histotechnician after a review of records confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS-209) form, personnel records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for three of four testing persons (TP-2, TP-3, TP-4) who perform moderate complexity testing in 2023 and 2024. Findings included: 1. Review of CMS 209 form revealed moderate complexity potassium hydroxide (KOH) procedures were performed by TP-2, TP-3, and TP-4. 2. Review of personnel records revealed annual competency assessments were not performed for TP-2, TP-3, and TP-4 in 2023 and 2024. 3. The laboratory was asked to provide documentation of competency assessments for 2023 and 2024 and none were provided. 4. During a phone interview on 05/07/2024 at 9:54 am, the Lead Histotechnician confirmed the above findings.